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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,216	04/18/2002	Hugo Seinfeld	HUBR-1204	8458

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EXAMINER	
ASHEN, JON BENJAMIN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,216	SEINFELD, HUGO	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-20* is/are pending in the application.

4a) Of the above claim(s) *6-14 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/6/02; 7/11/02;*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 15 and 19-20, in the reply filed on 10/21/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 6-14 and 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/21/2004.

Information Disclosure Statement

3. The information disclosure statement filed 2/6/2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the following references have not been considered: FR 2 713 487 and DE 25 47 696.

Claim Objections

4. Claims 15, 19 and 20 are objected to because of the following informalities: Claim 15 recites, "tot he" which is an evident typographical error. Claim 19 includes the genus and species names of *Herpes simplex* and *Varicella zoster* viruses in improper scientific format; *i.e.*, without the appropriate italics or capitalization. Claim 20 ends with two (2) periods (.). Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 15, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, claim 15 recites, "administering tot he (to the?) subject an active amount of 0.1mg and higher of xenogeneic oligo- and/or polyribonucleotides per unit dose" and claim 20 recites, "administering an active amount 0.1mg and higher of xenogeneic oligo- and/or polyribonucleotides in an anhydrous preparation per unit dose." In the instant case, the meaning of the claim language is so unclear that one of skill in the art cannot determine the metes and bounds of what is being claimed by "an active amount of 0.1 mg and higher per unit dose." How much higher the active amount per unit dose could be, for example, cannot be determined from the claim. Claim 19 recites the limitation "the

pharmaceutical composition of claim 25" in line 3. Since there is no claim 25, the metes and bounds of what is being claimed by a method comprising administering the "pharmaceutical composition of claim 25" cannot be determined.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 15 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

9. Claims 15 and 20 are drawn to methods treating Herpesviridae infections and/or skin tumors comprising administering xenogeneic oligo- and or polynucleotides. The instant claims are drawn to a broad genus of methods of treatment wherein any of a broad genus of xenogeneic oligo- and or polynucleotides are used to treat any and/or all of a large family of DNA containing viruses (the Herpesviridae) and/or a broad genus of skin tumors. In the instant case, the breadth of the claimed genus of treatments that employ any xenogeneic oligo- and/or polynucleotides to treat any Herpesviridae infection or any skin tumors, as claimed, is extremely broad and reads on a vast number

of xenogeneic oligo- and/or polynucleotide species that will function to treat of any of a vast number of infections caused by Herpesviridae viruses and/or skin tumors.

The specification as filed discloses a single example of xenogeneic oligo- and or polynucleotides species that will function in the method as claimed and only 2 species (in the patent sense, not the biological sense) of Herpesviridae infections and a single example of a skin tumor (a basalioma) that are treated by the method as claimed. The specification as filed also provides only general guidance as to what is encompassed by xenogeneic oligo- and/or polynucleotides of the invention. However, the specification as filed does not provide any disclosure of sufficiently detailed, relevant identifying characteristics of xenogeneic oligo- and or polynucleotides that will function to treat any infection by any member of the Herpesviridae viral family or any of the vast array of complex and multigenic dermal disorders that would be encompassed by any skin tumor, as claimed, thereby providing insufficient evidence that applicant was in possession of the claimed invention. In particular, no adequate written description is provided of xenogeneic oligo- and or polynucleotides that will function to a provide treatment of any infection caused by any member of the Herpesviridae and/or any skin tumor because the specification does not provide the specific structure of any particular xenogeneic oligo- and or polynucleotides that would correspond with the function of providing treatment of any infection caused by any member of the Herpesviridae and/or any skin tumor.

Therefore, the disclosure of the specification fails to provide a) specific guidance concerning what distinguishing identifying characteristic of the claimed xenogeneic

oligo- and or polynucleotides would correspond with the function of providing treatment commensurate with the scope of what is being claimed, and b) the structure of any particular xenogeneic oligo- and or polynucleotides that would correspond with the function to provide a treatment commensurate with what is being claimed. The general guidance provided by the specification in regards to the xenogeneic oligo- and/or polynucleotides of the invention is insufficient to indicate possession because it does not provide the specific guidance required to reasonably lead one of skill in the art to the instant invention as claimed. What is the specific structure of the xenogeneic oligo- and/or polynucleotides that would correspond with the function as claimed, of providing a treatment for any infection caused by any member of the Herpesviridae family of viruses and/or any skin tumor, for example?

Vas-Cath Inc. v. Mahurkar, 19USPQ2nd 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed (see page 1117). Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613.<

Therefore, Applicant has not provided adequate written description of their invention because Applicant has not shown how their invention was "ready for patenting" such as by the disclosure of the structure of xenogeneic oligo- and/or polynucleotides that function to treat any and/or all skin tumors, for example, that show that the claimed invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of any particular

species of structure of xenogeneic oligo- and/or polynucleotides that function to treat any and/or all skin tumors.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Draper et al. (WO 93/23569). The invention as set forth in claim 15 is a method of treating infections by Herpesviridae and/or skin tumors in a subject comprising administering an active amount of 0.1 mg or higher of xenogeneic oligo- and or polyribonucleotides per unit dose (claim 15) wherein the xenogeneic oligo- and or polyribonucleotides can be in an anhydrous preparation and the unit dose is administered once per recurrence (claim 20).

Draper et al. disclose a method for treatment of a virus caused disease by administering to a patient an enzymatic RNA molecule (pg. 4, lines 34-36) wherein the virus can be a herpes virus (pg. 71, example 10) and the ribozyme can be produced in high yield by expressing the ribozyme from a vector in a bacterial or eukaryotic cell (pg. 80, lines 4-8). These ribozymes would therefore constitute xenogeneic ribonucleotides in that they originate from an organism different from the one to be treated (as defined by applicant on page 2 of the specification as filed). The ribozymes of Draper et al. can

be formulated for topical administration with oleic acid in a liposome (thereby constituting an anhydrous preparation) (pg. 186, lines 30-37 bridge to the 1st paragraph of pg. 187) and the dosage can be between 100-200 mg/kg body weight/day, thereby constituting an active amount of 0.1 mg and higher the duration of the treatment of Draper et al. can extend continuously thru the course of the disease symptoms, thereby constituting a single administration per recurrence (pg. 191, lines 1-18).

Therefore, Draper et al. anticipate each and every aspect of claims 15 and 20.

12. Claims 15 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dirheimer et al. (U.S. Patent 4,213,970; 1st disclosed reference, the PTO-1449 filed 2/06/02, this application). The invention as set forth in claims 15 and 20 is a method of treating infections by Herpesviridae and/or skin tumors in a subject comprising administering an active amount of 0.1mg or higher of xenogeneic oligo- and or polyribonucleotides per unit dose (claim 15) wherein the xenogeneic oligo- and or polyribonucleotides can be in an anhydrous preparation and the unit dose is administered once per recurrence (claim 20).

Dirheimer et al. disclose and claim a method of treating viral infections in a warm blooded animal in need thereof comprising topically administering an antiviral composition comprising an effective amount (from 1-150 mg) of an antiviral eukaryotic transfer-ribonucleic acid (tRNA) (Claims 1-4, Col. 2, lines 30-42) wherein the viral infection to be treated can be herpes (Col. 2, line 33). The tRNA of Dirheimer et al. is extracted from yeast and is therefore "xenogeneic" as per Applicant's definition of

xenogeneic on page 2 of the specification as filed which states, "Xenogeneic in accordance with the present invention means that the ribonucleic acid originates from an organism different from the one to be treated therewith, i.e., those oligo- and/or polyribonucleotides which are not from the same organism as that to which the medicament is to be administered." The method of Dirheimer et al. is a method of treatment of an animal in need thereof and would therefore be a method wherein xenogeneic oligonucleotide and/or polyribonucleotides are administered once per recurrence because each recurrence would indicate that the animal was in need thereof.

Therefore, Dirheimer et al. anticipate each and every aspect of the claimed invention.

Conclusion

13. No claim currently under examination is in condition for allowance or free of the prior art searched.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba

SEAN MCGARRY
PRIMARY EXAMINER
1635